K082106

OCT 02 2008

Elcam Medical

SPECIAL 510(K) SUMMARY FOR ELCAM ANTIMICROBIAL CLOSED STOPCOCKS (DSS AND TSS)

DATE PREPARED: JULY 21, 2008

1. 510(K) OWNER NAME

Elcam Medical ACAL
Kibbutz BarAm, Merom HaGalil 13860, Israel

Submitter person name: Ms. Tali Hazan – R.A Specialist
Telephone: 972-4-6988875, *Fax:* 972-4-6980777, *E-mail:* tali@elcam.co.il

ELCAM MEDICAL'S U.S AGENT:
Elcam Medical, Inc.
2 University Plaza, Suite 620, Hackensack, NJ 07601, USA

Contact Person: Mr. Ehud Raivitz – CEO
Telephone: 201-457-1120, *Fax:* 201-457-1125,
E-mail: ehud@elcam-medical.com

2. DEVICE NAME

Common/Usual Name: *Antimicrobial Closed Stopcocks (DSS* and *TSS)*
Proprietary/Trade name: *Double Safe Stopcock (DSS)* and
Triple S afe Stopcock (TSS)
*Stopcock = the word "Stopcock" applies also to "Manifolds"

Classification: Elcam's *Antimicrobial Closed Swabable Stopcock* and *TSS* has been classified as **Class II** devices under the following classification names:

Classification Name	Product Code	21 CFR Ref.	Panel
Stopcock, I.V. Set	FMG	880.5440	General Hospital

3. PREDICATE DEVICES

Elcam's *Antimicrobial Closed Stopcocks (DSS and TSS)* are substantially equivalent to Elcam's *Antimicrobial Stopcock (B-Stop)* cleared under 510(k) number **K053405** and to Elcam's *Closed Swabable Stopcock* and *MRVLS* (**M**inimal **R**esidual **V**olume **L**uer-activated **S**wabable stopcock) cleared under 510(k) number **K060231**.

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4. MODIFIED DEVICE DESCRIPTION

Elcam Medical's ***Antimicrobial Closed Stopcocks (DSS and TSS)*** are a similar version of Elcam legally marketed stopcocks, cleared under 510(k) numbers K053405 and K060231, as identified in paragraph number 3 above.
Our *Antimicrobial DSS* and *TSS* combine two or three features of our legally marketed devices into one product contains these two or three protection lines as following described:

The ***Double Safe Stopcock (DSS)*** consists of our antimicrobial stopcock combined with our closed swabable luer-activated valve stopcock.

The closed swabable valve functions as a microbial barrier and the antimicrobial agent, impregnated in the stopcock body acts to prevent/reduce the growth of contaminants.
This configuration presents a stopcock with **two protection lines**:
(1) impregnated antimicrobial agent; **(2)** closed swabable valve.

The ***Triple Safe Stopcock (TSS)*** consists of the same platform of the antimicrobial stopcock together with our legally marketed *MRVLS* (**M**inimal **R**esidual **V**olume **L**uer-activated **S**wabable stopcock) design.
The two protection lines described above for the DSS exist in the TSS yet, the TSS has a third protection line which is the unique design of the MRVLS handle enables fluid flow around the handle and thus enables more thorough and continuous flushing of the entire stopcock fluid path. This configuration presents a stopcock with **three protction lines**:
(1) impregnated antimicrobial agent; **(2)** closed swabable valve; **(3)** MRVLS handle unique design.

5. INTENDED USE

Elcam *Antimicrobial Closed Stopcocks* (*DSS* and *TSS*) are indicated for fluid flow directional control and for providing access port(s) for administration of solutions. Typical uses include pressure monitoring, intravenous fluid administration and transfusion.

Both configurations have a feature of an antimicrobial agent using a compound containing silver.

The inclusion of an antimicrobial agent into the material formulation is intended to prevent/reduce the growth of contaminants on the device.

The device is NOT intended to be used as a treatment for patient infections.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Elcam's DSS and *TSS* are substantially equivalent to Elcam's legally marketed stopcocks cleared under 510(k) number K053405 and K060231. Elcam's new product and the predicate devices have the same indication for use, same shape, characteristics, materials, manufacturing technology and design. The modified device configurations provide even more protections than the predicates by combining all protection lines together.

There are no differences affecting the device's intended use or alter the device's fundamental scientific technology. The device is, therefore, as safe and as effective as the predicate device.

7. NONE CLINICAL PERFORMANCE DATA

Design verification tests results are supporting all labeling claims and substantial equivalency.
The modified device was tested with accordance to Elcam's legally marketed device specification and all acceptance criteria were met.

Biocompatibility and chemical tests, material characterization and risk assessment were previously performed for all patient-contact and fluid path materials consisting Elcam's modified device with satisfactory results.

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8. CONCLUSIONS

The evaluation of Elcam's *Antimicrobial Closed Stopcocks (DSS* and *TSS),* non-clinical tests demonstrate that the modified devices are as safe and as effective as the predicate devices. Therefore, we believe it is substantially equivalent to the Elcam's legally marketed devices identified as predicates.

Elcam Medical
BarAm 13860, Israel
Tel: 972-4-698-8120/1/2, Fax: 972-4-698-0777 sales@elcam.co.il
www.elcam-medical.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 02 2008

Ms. Tali Hazan
Regulatory Affairs Specialist
Elcam Medical A.C.A.L.
Kibbutz Bar-AM
D.N. Merom Hagalil
ISRAEL 13860

Re: K082106
Trade/Device Name: Antimicrobial Closed Stopcocks (*DSS and *TSS)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMG
Dated: September 7, 2008
Received: September 11, 2008

Dear Ms. Hazan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Antimicrobial Closed Stopcocks (*DSS and *TSS)

*DSS – Double Safe Stopcock
*TSS – Triple Safe Stopcock

Indications for Use: Elcam *Antimicrobial Closed Stopcocks (DSS* and *TSS)* are indicated for fluid flow directional control and for providing access port(s) for administration of solutions. Typical uses include pressure monitoring, intravenous fluid administration and transfusion.

Both configurations have a feature of an antimicrobial agent using a compound containing silver.

The inclusion of an antimicrobial agent into the material formulation is intended to prevent/reduce the growth of contaminants on the device.

The device is NOT intended to be used as a treatment for patient infections.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K082106

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(Posted November 13, 2003)